

REMARKS

Amendments

Support for the amendment to claim 26 is found in the specification, for example, on page 10, lines 2-23 and page 22, line 2. Support for new claims 51-63 is found, for example, in Figures 7, 8, 10, 11, and 13-16 and claims 43-49.

The Office Action

Claims 26-50 are pending. Claims 26-50 stand rejected for containing subject matter that is not described in the specification. Claims 26-29 stand further rejected as being anticipated by Khmelnsky et al. (Biochemistry 1992, 206:737-745 ; hereafter "Khmelnsky").

Rejections Under 35 U.S.C. § 112, first paragraph

Claims 26-50 stand rejected for reciting new matter. Applicants traverse this rejection as applied to amended claim 26.

Regarding the language "seven or more nitrogen atoms" in claim 26, the Examiner states that "the specification as filed ... does not disclose '300 Da' as a molecular weight." Applicants assert that one skilled in the art would know that a value of molecular weight is given in Daltons, since Dalton is the universal unit of molecular weight. The use of grams and moles in the Examples is an indication of the amount of a particular compound used in a synthesis or experiment and not the molecular weight. The

calculations used to determine seven nitrogen atoms from 300 Da are as follows. The molecular weight of a unit of ethylenimine ($-\text{CH}_2\text{CH}_2\text{NH}-$) is about 43 Da $((2 \times 12) + (5 \times 1) + (1 \times 14))$, where the atomic weights of C, H, and N are about 12, 1, and 14, respectively. Seven units of ethylenimine weigh 301 Da (7×43). Since each ethylenimine unit has one nitrogen atom, a polyethylenimine having a molecular weight of 300 Da or more necessarily has seven or more nitrogen atoms. In reply to the Examiner's statement that "Applicants have not accounted for the contribution of other molecules in the polyethylenimine structure," Applicants have now amended the claim to require that the base skeleton has seven or more nitrogen atoms. Support for this amendment is found in the discussion on page 10, lines 2-23 of the specification in which it is clear that the molecular weights listed are for the polyalkylenimine base skeletons that may be used in the synthesis of the compositions of the invention. For example, a molecular weight of 600 is given for EPOMINE, which is a commercially available compound that may be used in the manufacture of the instantly claimed compositions.

Regarding the language "a base skeleton that does not comprise a carbonyl group" in claim 26, Applicants have amended claim 26 to remove this language, and the rejection may be withdrawn. Applicants note, however, that, in general, the term "polyalkylenimine" describes a polymer having a base skeleton including only alkylene (e.g., $-\text{CH}_2-$) and imine (e.g., $-\text{NH}-$) functional groups, which by definition do not contain carbonyl (i.e., $-\text{C}(\text{O})-$) groups. Since alkyleneimine refers only to the base skeleton,

carbonyl groups may be present in pendant groups (R' or R¹) attached to the base skeleton, as described in Formulas I-III on pages 11-12 of the specification.

Based on the foregoing remarks, the rejection of claims 26-50 for new matter should be withdrawn.

Rejections Under 35 U.S.C. § 102 (b)

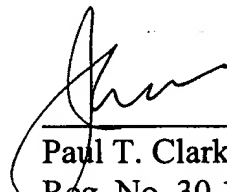
Claims 26-29 stand rejected for anticipation by Khmelnitsky. As applied to amended claim 26, Applicants traverse this rejection. Claim 26, as amended, requires compositions with a degree of substitution on the nitrogen atoms of 24.5% or less. Since the nitrogen atoms in the compositions of Khmelnitsky have a degree of substitution of 70% (pg. 740, second column), they do not fall within claim 26 as amended, and Khmelnitsky does not anticipate claims 26-29. The rejection for anticipation may be withdrawn.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. Enclosed is a petition to extend the period for reply for three months, to and including November 21, 2002, and a check in the amount of \$460.00 for the required fee. In addition, a check for \$647.00 is enclosed for the additional claims fee. If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 21 November 2002



Paul T. Clark
Reg. No. 30,162
JAMES D. DeCamp
Reg. No. 43,580

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045



21559
PATENT, TRADEMARK OFFICE

\\CLARK-W2K1\documents\50026\50026.024001 Reply to Office Action dated 05.21.02.doc

Version with Markings to Show Changes Made

A marked up version of claim 26 is as follows.

26. (Twice Amended) A [water soluble] composition comprising a polyalkylenimine or a salt thereof, wherein said polyalkylenimine or said salt comprises (a) two or more hydrophobic groups [,] and (b) a base skeleton comprising seven or more nitrogen atoms, [and (c) a base skeleton that does not comprise a carbonyl group] wherein the degree of substitution on said nitrogen atoms is \leq 24.5%.